



Drug Enforcement Administration

[Docket No. DEA-750]

Bulk Manufacturer of Controlled Substances Application: Janssen Pharmaceuticals Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Janssen Pharmaceuticals Inc., has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Such persons may also file a written request for a hearing on the application on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on November 11, 2020, Janssen Pharmaceuticals Inc., 1440 Olympic Drive, Athens, Georgia, 30601-1645, applied to be registered as an bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled Substance	Drug Code	Schedule
Methylphenidate	1724	II
Hydromorphone	9150	II
Hydrocodone	9193	II
Oripavine	9330	II

Thebaine	9333	II
Tapentadol	9780	II

The company plans to manufacture the above-listed controlled substances in bulk for distribution to its customers. No other activities for these drug codes are authorized for this registration.

William T. McDermott,

Assistant Administrator.

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